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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,466	04/26/2001	Hiroyasu Kokubo	35576/233803	8005

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EXAMINER
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SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/842,466

Applicant(s)

KOKUBO ET AL.

Examiner

Humera N Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 June 2003 (paper no. 12).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 10
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**  
**Status of the Application**

Receipt of the request for extension of time (1 month) and the Amendment, both filed 06/02/03 is acknowledged.

The 35 U.S.C. 112 second paragraph rejections have been withdrawn.

Claims 6-20 are pending. Claims 6, 7, 10 and 15-17 have been amended. Claim 1 has been cancelled. Claims 6-20 are rejected.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 6-8, 10 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Berta (US Pat. No. 4,820,524).**

Berta discloses a solid, multi-colored medicament preparation having a gelatinous coating, wherein the coating layer provides two or more different colors (see reference col. 4, lines 39-42).

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The medicament may be in the form of a caplet and contains a layer of gelatin as a single coating on the caplet core.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 9, 11-14 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berta (US Pat. No. 4,820,524).**

As discussed above, Berta teaches a solid, multi-colored medicament preparation having a gelatinous coating, wherein the coating layer provides two or more different colors (see reference col. 4, lines 39-42).

Berta also teaches a method for coating the solid cores, such as caplets, to produce simulated, capsule-like medicaments. Berta teaches that one objective of the invention is to provide a simulated, capsule-like medicament having a gelatinous coating capable of being provided in two or more colors. Another objective is to provide a heavy layer of gelatin as a *single* coating to cover imperfections inherent on the caplet core (col. 4, lines 12-56). Suitable coatings to be used are gelatinous materials, such as methyl cellulose, calcium alginate and gelatin. Additional ingredients include plasticizers, preservatives, coloring agents and opacifying agents (col. 8, lines 20-47).

Berta teaches a solid, multi-colored medicament wherein colorings can be added to the coatings to produce *opaque* or *transparent* colors, such as red, white, pink, green, reddish brown, blue, yellow and black, for example. Colored medicaments are necessary to give a specialty product a distinctive appearance. To form white medicaments or an opaque colored coating, titanium dioxide is often added to the gelatin (col. 9, lines 1-7).

Berta teaches that the solid, multi-colored medicament preparation additionally comprises various coating patterns (see Figs. 8 a-d and col. 5, lines 28-29). Berta does not explicitly teach a logo, letters or a bar code on the medicament. However, the inclusion of logos, bar codes or letters, as instantly claimed does not make the invention patentable since variations in designs or patterns in solid medicament forms is commonly and routinely practiced in the pharmaceutical art.

Berta teaches a solid preparation comprising a gelatinous coating that provides two or more colors wherein the medicament is smooth, shiny, multi-colored and has various coating patterns. These medicaments are pleasing to the eye, are easier to swallow than prior medicaments and offer a distinctive appearance, as similarly desired by the applicant.

### ***Response to Arguments***

Applicant's arguments filed 06/02/03 have been fully considered but they are not persuasive.

The applicant argued over the 35 USC 102(b) rejection over Berta ('524) and the 35 USC 103(a) rejections of claims 9-14 and 18-20 stating, "Claim 10 is a solid preparation coated with a continuous film coating layer comprising at least one colorant. At least a portion of the film-coating layer is exposed to radiation under conditions to modify the color of the colorant so as to provide a coating layer with at least two different colors. The examiner indicated during the interview that Berta et al. do not teach or suggest the use of ultraviolet radiation to effect a color change in a tablet."

These arguments have been fully considered, but were not found to be persuasive. A product is being claimed in the instant invention, not the process by which it was prepared. It is the product that must be patentable. More particularly, the claims are drawn to a product that has 2 distinct colors as essentially taught by the Berta reference (see col. 4, lines 39-56 where there is the teaching of a gelatinous

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coating capable of being provided in two or more colors. The gelatin coating can be provided as a single coating). Because of this teaching, the claims are fully met.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703)

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308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*hns*

July 18, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600